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APPLICATION FOR UNITED STATES LETTERS PATENT

for

Focused Ultrasound Ablation Devices Having Selectively Actuatable Emitting Elements and Methods of Using the Same

by

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PATENT APPLICATION

Title: Focused Ultrasound Ablation Devices Having Selectively Actuatable Emitting Elements and Methods of Using the Same

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CROSS-REFERENCE TO RELATED PATENT APPLICATIONS

This application is a continuation of co-pending U.S. patent application Serial No. 09/487,710 filed January 19, 2000, the disclosure of which is incorporated herein by reference.

This application is related to U.S. patent applications Serial No. 09/487,708 filed January 19, 2000, now abandoned and entitled Methods of Soft Palate Reduction By Thermal Ablation Using High Intensity Focused Ultrasound, Serial No. 09/487,707 filed January 19, 2000, now U.S. Patent No. 6,413,254 and entitled Methods of Tongue Base Reduction By Thermal Ablation Using High Intensity Focused Ultrasound, Serial No. 09/487,709 filed January 19, 2000, now abandoned and entitled Methods of Tonsil Reduction By Thermal Ablation Using High Intensity Focused Ultrasound, Serial No. 09/487,706 filed January 19, 2000, now abandoned and entitled Methods of Turbinate Or Other Soft Tissue Reduction By Thermal Ablation Using High Intensity Focused Ultrasound, Serial No. 09/488,844 filed January 21, 2000, now U.S. Patent No. 6,361,531 and entitled Methods of Skin Rejuvenation By Thermal Stimulation Using High Intensity Focused Ultrasound, and Serial No. 09/488,844 filed January 21, 2000, now U.S. Patent No. 6,361,531 and entitled Focused Ultrasound Ablation Devices Having Malleable Handle

Shafts and Methods of Using the Same, the disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

Field of the Invention:

The present invention relates generally to the treatment of anatomical tissue with high intensity focused ultrasound energy and, more particularly, to focused ultrasound ablation devices having a plurality of selectively actuatable ultrasound emitting elements by which lesions of selected sizes and/or patterns are formed in anatomical tissue and to methods of thermal ablation using the same.

Brief Description of the Related Art:

When high intensity ultrasound energy is applied to anatomical tissue, significant physiological effects may be produced in the anatomical tissue resulting from thermal and/or mechanical changes or effects in the tissue. Thermal effects include heating of the anatomical tissue; and, when the tissue is heated to a sufficiently high temperature, tissue damage such as coagulative necrosis is produced. Mechanical effects include liquefaction, cavitation and/or fragmentation of the anatomical tissue. In order to produce thermal effects in anatomical tissue, ultrasound treatment devices or applicators having ultrasound emitting members such as transducers have been used to emit ultrasound energy which is applied to anatomical tissue by positioning the ultrasound emitting members adjacent or in contact with the tissue or by coupling the ultrasound emitting members to the tissue via an acoustic coupling medium. By focusing the ultrasound energy at a specific target location,

region, volume or area within the tissue, thermal effects can be confined to the specific location, region, volume or area, and such location, region, volume or area can be remote from the ultrasound emitting member.

With the use of high intensity focused ultrasound (HIFU), a discrete or defined target location, region, volume or area within a larger mass, body or area of anatomical tissue can be subjected to high intensity ultrasonic energy while surrounding non-target anatomical tissue is subjected to much lower intensity ultrasonic energy. In this manner, tissue at the target location, volume, region or area can be heated to a sufficiently high temperature so as to cause a desired thermal effect such as tissue damage, ablation, coagulation, denaturation, destruction or necrosis while tissue surrounding the target location, volume, region or area is not heated to damaging temperatures and, therefore, is preserved. Heating of the target location, volume, region or area, with the high intensity focused ultrasound, to an ablative temperature creates an ablative lesion in the tissue at the target location, volume, region or area that is subsequently naturally degraded and absorbed by the patient's body and is thusly eliminated such that the remaining body, mass or area of tissue is of smaller volume or size due to the absence of the ablated tissue.

The use of high intensity focused ultrasound to eliminate a target location, volume, region or area of tissue within a larger mass, body or area of anatomical tissue presents many advantages including minimization of trauma and pain for the patient, elimination of the need for a surgical incision, stitches and exposure of internal tissue, avoidance of damage to tissue other than that which is to be treated or removed, lack of a harmful cumulative effect from the ultrasound energy on the surrounding non-target tissue, reduction in treatment costs, elimination of the need in many cases for general anesthesia,

reduction of the risk of infection and other complications, avoidance of blood loss, and the ability for high intensity focused ultrasound procedures to be performed in non-hospital sites and/or on an out-patient basis.

Various ultrasound treatment devices and/or methods for treating anatomical tissue with ultrasound have been proposed as represented by U.S. Patents No. Re. 33,590 to Dory, No. 3,990,452 to Murry et al, No. 4,658,828 to Dory, No. 4,807,633 to Fry, No. 4,858,613 to Fry et al, No. 4,951,653 to Fry et al, No. 4,955,365 to Fry et al, No. 5,033,456 to Pell et al, No. 5,036,855 to Fry et al, No. 5,054,470 to Fry et al, No. 5,065,761 to Pell, No. 5,080,101 to Dory, No. 5,080,102 to Dory, No. 5,117,832 to Sanghvi et al, No. 5,134,988 to Pell et al, No 5,143,074 to Dory, No. 5,150,711 to Dory, No. 5,150,712 to Dory, No. 5,158,070 to Dory, No. 5,222,501 to Ideker et al, No. 5,267,954 to Nita, No. 5,269,291 to Carter, No. 5,269,297 to Weng et al, No. 5,295,484 to Marcus et al, No. 5,304,115 to Pflueger et al, No. 5,312,328 to Nita et al, No. 5,318,014 to Carter, No. 5,342,292 to Nita et al, No. 5,354,258 to Dory, No. 5,380,274 to Nita, No. 5,391,197 to Burdette et al, No. 5,397,301 to Pflueger et al, No. 5,409,002 to Pell, No. 5,417,672 to Nita et al, No. 5,431,621 to Dory, No. 5,431,663 to Carter, No. 5,447,509 to Mills et al, No. 5,474,530 to Passafaro et al, No. 5,492,126 to Hennige et al, No. 5,501,655 to Rolt et al, No. 5,520,188 to Hennige et al, No. 5,542,917 to Nita et al, No. 5,620,479 to Diederich, No. 5,676,692 to Sanghvi et al, No. 5,728,094 to Edwards, No. 5,730,719 to Edwards, No. 5,733,315 to Burdette et al, No. 5,735,280 to Sherman et al, No. 5,738,114 to Edwards, No. 5,746,224 to Edwards, No. 5,762,066 to Law et al, No. 5,800,379 to Edwards, No. 5,800,429 to Edwards, No. 5,800,482 to Pomeranz et al, No. 5,807,308 to Edwards, No. 5,817,049 to Edwards, No. 5,823,197 to Edwards, No. 5,827,277 to Edwards, No.

5,843,077 to Edwards, No. 5,871, 524 to Knowlton, No. 5,873,845 to Cline et al, No. 5,873,902 to Sanghvi et al, No. 5,879,349 to Edwards, No. 5,882,302 to Driscoll, Jr. et al, No. 5,895,356 to Andrus et al and No. 5,938,608 to Bieger et al.

In particular, focused ultrasound ablation devices used to thermally damage, ablate, coagulate, denature, cauterize, necrotize or destroy a target volume of tissue are exemplified by U.S. patents No. Re. 33,590 to Dory, No. 4,658,828 to Dory, No. 4,807,633 to Fry, No. 4,858,613 to Fry et al, No. 4,951,653 to Fry et al, No. 4,955,365 to Fry et al, No. 5,036,855 to Fry et al, No. 5,054,470 to Fry et al, No. 5,080,101 to Dory, No. 5,080,102 to Dory, No. 5,117,832 to Sanghvi et al, No. 5,143,074 to Dory, No. 5,150,711 to Dory, No. 5,150,712 to Dory, No. 5,295,484 to Marcus et al, No. 5,354,258 to Dory, No. 5,391,197 to Burdette et al, No. 5,431,621 to Dory, No. 5,492,126 to Hennige et al, No. 5,501,655 to Rolt et al, No. 5,520,188 to Hennige et al, No. 5,676,692 to Sanghvi et al, No. 5,733,315 to Burdette et al, No. 5,762,066 to Law et al, No. 5,871,524 to Knowlton, No. 5,873,845 to Cline et al, No. 5,873,902 to Sanghvi et al, No. 5,882,302 to Driscoll, Jr. et al, No. 5,895,356 to Andrus et al and No. 5,938,608 to Bieger et al. The focused ultrasound ablation devices are used to ablate various target areas in or on the bodies of patients including the brain, prostate, heart, urethra, blood vessels, deep seated tissue and tumors, liver, kidney, skin, breast, stomach and pancreas.

Ablation of anatomical tissue of the head and/or neck in order to reduce or eliminate such tissue in the treatment of various airway related disorders has also been proposed as illustrated by U.S. patents No. 5,423,812 to Ellman et al, Nos. 5,456,662, 5,514,131, 5,624,439, 5,674,191,5,707,349, 5,718,702, 5,728,094, 5,730,719, 5,738,114, 5,743,870, 5,743,904, 5,746,224, 5,800,379, 5,800,429, 5,807,308, 5,817,049, 5,823,197, 5,827,277,

5,843,077 and 5,879,349 to Edwards and WO 97/43970. The areas ablated include the soft palate, uvula, tongue, tonsils, adenoids and turbinates. U.S. patent No. 5,423,812 relates to electrosurgical stripping of tissue. U.S. patents No. 5,456,662, No. 5,514,131, No. 5,624,439, No. 5,674,191, No. 5,707,349, No. 5,718,702, No. 5,728,094, No. 5,730,719, No. 5,738,114, No. 5,743,870, No. 5,743,904, No. 5,746,224, No. 5,800,379, No. 5,800,429, No. 5,807,308, No. 5,817,049, No. 5,823,197, No. 5,827,277, No. 5,843,077, No. 5,879,349 and WO97/43970 disclose RF ablation using tissue penetrating electrodes. U.S. patents No. 5,707,349, No. 5,728,094, No. 5,730,719, No. 5,738,114, No. 5,746,224, No. 5,800,379, No. 5,800,429, No. 5,807,308, No. 5,817,049, No. 5,823,197, No. 5,827,277, No. 5,843,077 and No. 5,879,349 refer to ultrasound as a possible source of ablative energy.

Prior focused ultrasound ablation devices typically have ultrasound emitting members, commonly including transducers, for emitting ultrasound energy and focusing the ultrasound energy at target areas in anatomical tissue in order to effect thermal ablation at the target areas. Exemplary focused ultrasound ablation devices employing transducers as the ultrasound emitting members thereof are disclosed in U.S. patents Nos. 4,658,828 to Dory, 4,858,613, 4,951,653, 4,955,365, 5,036,855 and 5,054,470 to Fry et al, 5,080,101 and 5,080,102 to Dory, 5,117,832 to Sanghvi et al, 5,143,074, 5,150,711 and 5,150,712 to Dory, 5,295484 to Marcus et al, 5,354,258 to Dory, 5,391,197 to Burdette et al, 5,431,621 to Dory, 5,492,126 to Hennige et al, 5,501,655 to Rolt et al, 5,520,188 to Hennige et al, 5676,692 to Sanghvi et al, 5,762,066 to Law et al, 5,873,845 to Cline et al, 5,873,902 to Sanghvi et al, 5,882,302 to Driscoll, Jr. et al, 5,895,356 to Andrus et al, 5,928,169 to Schätzle et al, 5,938,608 to Bieger et al and Re. 33,590 to Dory.

Some prior focused ultrasound ablation devices employ arrays or pluralities of transducer elements as the ultrasound emitting members, respectively, as represented by U.S. patents Nos. 4,658,828, 5,080,101, 5,080,102, 5,143,074, 5,150,712 and Re. 33,590 to Dory, 5,391,197 to Burdette et al, 5,501,655 to Rolt et al, 5,520,188 to Hennige et al, 5,928,169 to Schätzle et al and5,938,608 to Bieger et al. U.S. patents Nos. 4,658,828, 5,080,101, 5,080,102, 5,150,712, 5,501,655, 5,520,188, 5,928,169, 5,938,608 and Re. 33,590 disclose the transducer elements as being actuated or driven in phase-offset relation to one another in order to change the location at which the ultrasound energy is focused in anatomical tissue. U.S. patents Nos. 5,746,224 and 5,800,429 to Edwards disclose an energy delivery device comprising one or more ring electrodes to which RF energy may be independently delivered to effect thermal ablation of tissue. Ultrasound is merely referred to as a possible source of ablative energy.

In order to enhance the efficacy of focused ultrasound ablation procedures, it would be desirable to customize or tailor lesions to be formed in particular patients. For example, it would be desirable for a single focused ultrasound ablation device to be capable of forming lesions of various sizes and/or configurations or patterns in anatomical tissue including lesions of various irregular or discontinuous patterns. Also, it would be desirable for a focused ultrasound ablation device to be capable of forming a lesion comprising disconnected lesion segments. By providing a focused ultrasound ablation device having the foregoing attributes, optimum lesion characteristics can be selected for particular patients based on assessments made by surgeons or other medical personnel at the time of surgery. However, prior focused ultrasound ablation devices, as exemplified by the

above-mentioned patents, do not provide focused ultrasound emitting members having the foregoing attributes.

SUMMARY OF THE INVENTION

Accordingly, it is a primary object of the present invention to overcome the various disadvantages of prior focused ultrasound ablation devices.

It is also an object of the present invention to provide a focused ultrasound ablation device having an ultrasound emitting member capable of forming lesions of various preselected configurations in anatomical tissue.

Another object of the present invention is to provide a focused ultrasound ablation device having an ultrasound emitting member capable of forming a lesion comprising a plurality of disconnected lesion segments in anatomical tissue.

A further object of the present invention is to selectively actuate less than all of a plurality of ultrasound emitting elements of a focused ultrasound emitting member in order to form a lesion of selected size and/or configuration in anatomical tissue.

An additional object of the present invention is to increase the diversity of sizes and/or configurations of lesions capable of being formed in anatomical tissue.

It is also an object of the present invention to electronically control the actuation of selected ones of a plurality of ultrasound emitting elements of a focused ultrasound emitting member to form a lesion of optimal size and/or configuration in anatomical tissue of a patient.

The present invention also has as an object to provide a multi-array transducer including a plurality of transducer elements that are selectively actuatable to form lesions of various preselected sizes and/or configurations in patients.

Some of the advantages of the present invention are that the outcome of ultrasound ablation procedures in various areas of the body is greatly enhanced, a single focused ultrasound ablation device can optimally be used in various ablation procedures in various areas of the body, anatomical tissue around, between or surrounding the lesion segments can be left lesion free, a focused ultrasound emitting member having a particular array of transducer elements can be used to form lesions corresponding in size and/or configuration to the size and/or configuration of the array as well as lesions having sizes and/or configurations different from the size and/or configuration of the array, the focused ultrasound emitting member can be coupled with a handle for hand-held use and operation thereof, the focused ultrasound ablation device does not have to be customized for use in a specific area of the body, and the focused ultrasound emitting member can be provided in a focused ultrasound ablation device provided as a standardized instrument capable of being used in or on a wide variety of areas of patients' bodies.

These and other objects, advantages and benefits are realized with the present invention as generally characterized in a focused ultrasound ablation device including an ultrasound emitting member having a plurality of individual ultrasound emitting elements arranged thereon in an array. The ultrasound emitting elements are actuatable to emit ultrasound energy and focus the emitted ultrasound energy a predetermined distance from the ultrasound emitting member such that the ultrasound energy is focused within anatomical tissue adjacent which the ultrasound emitting member is placed. The

ultrasound energy is of relatively higher intensity where focused within the anatomical tissue, causing the anatomical tissue to be heated to an ablative temperature to form an internal lesion within the tissue. The ultrasound emitting elements are selectively, independently actuatable, allowing selected ones of the ultrasound emitting elements to be actuated to emit ultrasound energy to obtain a lesion of desired or selective size and/or surface configuration in the tissue of a particular patient. The lesion size and/or surface configuration corresponds to the locations and/or pattern of the ultrasound emitting elements selected for actuation. In this manner, lesion characteristics can be optimally selected for particular patients and particular ablation procedures to be performed. In a preferred embodiment, the ultrasound emitting elements are transducer elements including piezoelectric elements that emit ultrasound energy in response to an electric signal supplied thereto, and selected ones of the transducer elements are selected for actuation by selectively coupling the selected elements to an electrical signal.

A method of thermal ablation of anatomical tissue according to the present invention is generally characterized by the steps of selecting selected ones of a plurality of ultrasound emitting elements, arranged in an array on an ultrasound emitting member, for actuation to emit ultrasound energy in accordance with a desired size and/or configuration of a lesion to be formed in anatomical tissue of a patient, positioning the ultrasound emitting member adjacent or in contact with the anatomical tissue at a location aligned with a desired site for the lesion in the tissue, actuating the selected ones of the ultrasound emitting elements to emit ultrasound energy, focusing the ultrasound energy with the selected ones of the ultrasound emitting elements so that the ultrasound energy is focused a predetermined depth within the tissue and heating the tissue with the focused ultrasound

energy to form an internal lesion within the tissue having the desired size and/or configuration.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a broken perspective view, partly schematic, illustrating a focused ultrasound ablation device incorporating a focused ultrasound emitting member according to the present invention.

Fig. 2 is a broken side view, partly in section, depicting actuation of all of a plurality of ultrasound emitting elements of the ultrasound emitting member to emit ultrasound energy and focus the ultrasound energy in anatomical tissue to form a lesion.

Fig. 3 is a broken top view, illustrating the surface configuration of the lesion of Fig. 2.

Fig. 4 is a broken perspective view illustrating actuation of selected ones of the plurality of ultrasound emitting elements.

Fig. 5 is a broken top view illustrating the surface configuration of a lesion formed in tissue with the focused ultrasound emitting member when actuated as shown in Fig. 4.

Fig. 6 is a broken perspective view illustrating actuation of selected alternative ones of the plurality of ultrasound emitting elements.

Fig. 7 is a broken top view illustrating the surface configuration of a lesion formed in tissue with the focused ultrasound emitting member when actuated as depicted in Fig. 6.

Fig. 8 is a perspective side view illustrating an alternative focused ultrasound ablation device incorporating a modified focused ultrasound emitting member according to the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

A high intensity focused ultrasound ablation device 11 incorporating a focused ultrasound emitting member 12 according to the present invention is illustrated in Fig. 1. The focused ultrasound ablation device 11 includes ultrasound emitting member or element 12, an elongate handle shaft or handle body 14 having a distal end 16 at which the ultrasound emitting member 12 is disposed and a handle or handpiece 17 coupled to a proximal end 19 of handle shaft 14. As shown in Fig. 2, the ultrasound emitting member 12 includes a transducer 20 carried by a housing 22 and capable of generating and emitting ultrasound energy in response to being supplied with electrical power from a power supply 18. The transducer 20 includes a plurality of individual ultrasound emitting elements, transducers or transducer elements 23, each including a piezoelectric element 24 that vibrates to produce ultrasound energy when electrical current is supplied thereto. The transducer elements 23 have a focusing configuration or geometry that results in the ultrasound energy produced thereby being focused a fixed distance from the ultrasound emitting member 12. The transducer elements 23 have a partial spherical, concave configuration causing the ultrasound energy generated thereby to be focused, as shown by arrows in Fig. 2, at focusing zones P.

The transducer elements 23 are arranged in an array on or in housing 22; and, therefore, the transducer 20 may be considered a multi-array transducer. In the case of focused ultrasound emitting member 12, the transducer elements 23 are arranged in a planar array of five rows R and six columns C, although the transducer elements can be arranged in any number of rows and columns depending on the number of transducer

elements provided in the ultrasound emitting member . In the case of focused ultrasound emitting member 12, each row R has an equal number of transducer elements, and each column C has an equal number of transducer elements. It should be appreciated that any number of transducer elements can be provided in each row and column and that the numbers of transducer elements provided in each row and column can be the same or different. The transducer elements 23 can be referenced by their location in the array. For example, the transducer elements in the first row, first column can be designated transducer element R1C1, the transducer elements in the first row, second column can be designated transducer element R1C2 and so on. The transducer elements of each row are disposed close to one another, and the transducer elements of each column are disposed close to one another such that there is minimal space between adjacent transducer elements 23. As explained further below, the transducer elements 23 are selectively, independently actuatable to selective emit or not emit ultrasound energy.

The transducers 23 can be designed in various ways as known in the art. In the case of transducer 20, the transducers or transducer elements 23 each comprise a layer of piezoelectric material carried by housing 22 and forming the piezoelectric elements 24. The piezoelectric elements 24 are recessed from a planar external surface 34 of housing 22. The piezoelectric elements 24 are curved in a direction inwardly of surface 34 such that ultrasound energy generated by elements 24 is emitted from focused ultrasound emitting member 12 in a direction perpendicular to surface 34 for focusing at the focusing zones P, which are spaced outwardly of surface 34. Accordingly, surface 34 is an active surface or face of the ultrasound emitting member 12 which, when positioned externally adjacent or in contact with a mass, body or area of anatomical tissue A, results in the

ultrasound energy emitted by transducer 20 being focused at zones P, which will be disposed within the anatomical tissue A as shown in Fig. 2.

Each focusing zone P is in line with a central axis of the corresponding piezoelectric element 24. Each focusing zone P is disposed a fixed predetermined distance D from a plane containing the surface 34, the distance D for each focusing zone P being perpendicular to the surface 34. Therefore, the focusing zones P will also be disposed a predetermined perpendicular distance or a calculable or determinable perpendicular distance from an external tissue surface 41 of tissue A with which the surface 34 is placed in contact or adjacent thereto. Where the surface 34 is placed in contact with the external tissue surface 41, the perpendicular distance that zones P are disposed from external tissue surface 41 will be the same as the predetermined distance D as shown in Fig. 2. Where the surface 34 is not placed in contact with the external tissue surface 41 but, rather, is spaced from the external tissue surface 41 by a known amount, for example, the perpendicular distance that zones P are disposed from the external tissue surface 41 will correspond to distance D minus the distance that the surface 34 is spaced from the external tissue surface 41. Where the surface 34 is spaced from the external tissue surface 41, an acoustic coupling medium can be disposed between the external tissue surface 41 and the member 12 as disclosed in the patent applications incorporated herein by reference and entitled Methods of Soft Palate Reduction By Thermal Ablation Using High Intensity Focused Ultrasound, Methods of Tongue Base Reduction By Thermal Ablation Using High Intensity Focused Ultrasound, Methods of Tonsil Reduction By Thermal Ablation Using Soft Tissue Reduction By Thermal Ablation Using High Intensity Focused Ultrasound, Methods of Skin Rejuvenation By Thermal Stimulation Using High

Intensity Focused Ultrasound and Focused Ultrasound Ablation Devices Having Malleable Handle Shafts and Methods of Using the Same.

Since the ultrasound is focused at zones P, the ultrasound is of greater or higher intensity at focusing zones P and is thusly focused or concentrated at the focusing zones P, causing tissue A at the focusing zones P to be heated to an ablative temperature. When all of the transducer elements 23 are actuated, as shown in Fig. 2, heating of tissue A will occur at a focusing zone P for each transducer element 23. since the transducer elements 23 are disposed close to one another, the areas of tissue A between the focusing zones P are also heated to an ablative temperature due to the dispersal or spread of heat from the focusing zones P. Accordingly, a discrete, definitive lesion 30 is formed in the tissue A at a lesion or target area 28 while the temperature of the tissue A surrounding the lesion or target area 28 remains below damaging levels such that the surrounding tissue is undamaged and preserved. When all of the transducer elements 23 are actuated, a target or lesion area of specific configuration and size is created within the body, mass or area of anatomical tissue A for the transducer 20 in accordance with the intensity level of the emitted ultrasound energy and the duration or time of ultrasound energy delivery to the tissue. Accordingly, a lesion 30 having a specific length, width and depth is formed at the target or lesion area 28. Figs 2 and 3 illustrate the lesion 30 formed in tissue A when all of the transducer elements 23 are actuated. The lesion 30 has a generally rectangular configuration with a predetermined length and width dictated by the configuration of the array and a predetermined depth dictated by the length of the zones P.

The housing 22 can have various external configurations and sizes in accordance with the size, configuration and design of transducer 20 and the array in which the

transducer elements 23 are arranged. In the case of ultrasound emitting member 12, the housing 22 has a generally rectangular external configuration with rounded or blunt corners and/or edges to avoid damage to anatomical tissue. It should be appreciated that the transducer elements 23 can be disposed within the housing with the ultrasound energy generated by transducer 20 being transmitted or emitted through or from a wall of the housing, such wall being made of material through which ultrasound energy can pass and defining the active face for the ultrasound emitting member. Of course, a surface of the transducer itself can define the active face for the ultrasound emitting member. The active face 34 for ultrasound emitting member 12 is parallel to a longitudinal axis of member 12 so that the predetermined or determinable distances for zones P beyond the active face 34 and the external tissue surface 41 are perpendicular to the longitudinal axis. It should be appreciated, however, that the active face 34 can be disposed at various angles to the longitudinal axis whereby the predetermined or determinable distances for zones P beyond the active face and the external tissue surface 41 may be perpendicular to the active face but non-perpendicular to the longitudinal axis. The active face 34 may be rigid or flexible or deformable depending on procedural use. The active face and/or transducer 20 may be designed to conform to the shape of the tissue surface against which the active face is placed. Of course, where soft tissue is being ablated, the soft tissue may conform to the shape of the active face 34 and/or transducer 20 where the active face 34 and/or transducer 20 is/are more rigid than the tissue.

The handle shaft 14 comprises an elongate, hollow or tubular member of sufficient length to position the ultrasound emitting member 12 at various operative sites in or on the body of a patient while the handle 17 is maintained at a remote location, typically externally

of the patient's body. Preferably, the handle shaft 14 is malleable as disclosed in the application entitled Focused Ultrasound Ablation Devices Having Malleable Handle Shafts and Methods of Using the Same, the disclosure of which is incorporated herein by reference. The distal end 16 of handle shaft 14 is coupled with the ultrasound emitting member 12 by being disposed on or within an end wall of housing 22 or by extending through the end wall of housing 22 to be disposed within the housing.

The handle 17 has a forward end coupled to the proximal end 19 of handle shaft 14 and has a rearward end. The handle 17 preferably has a configuration to facilitate grasping by a surgeon or other operator. In the case of focused ultrasound ablation device 11, the handle 17 has a cylindrical body with raised, external annular segments 32. The segments 32 are longitudinally spaced from one another, and one or more controls or switches 33, such as push button controls or switches 33, may be disposed on handle 17 between spaced segments 32. The one or more controls or switches 33, where provided, may be used to effect operation of the focused ultrasound ablation device 11. It should be appreciated that the handle 17 can be provided without controls or switches in which case operation of the focused ultrasound ablation device may be effected by one or more controls or switches located on the power supply, a controller 44and/or a dedicated structure such as a foot pedal. Where the one or more controls or switches are provided on the handle 17, as illustrated for focused ultrasound ablation device 11, the one or more controls or switches is/are desirably placed at a location on handle 17 amenable to convenient operation thereof by the hand of the surgeon or other operator grasping the handle 17. As shown in Fig. 1, the push button controls or switches 33 are accessible and operable by a finger of the hand grasping the handle 17 for one-handed operation of

ablation device 11. The proximal end 19 of handle shaft 14 is coupled with handle 17 at the forward end thereof and, in particular, at a forward wall of the handle. The proximal end 19 may be disposed on or within the forward wall or may extend through the forward wall to be disposed within the handle 17. With the proximal end 19 of the handle shaft 14 thusly coupled to the handle 17, the longitudinal axis of handle 17 is coaxially aligned with the longitudinal axis of handle shaft 14 at proximal end 19.

One or more electrical transmission wires 42 is/are connected to the transducer 20 and extend through the handle shaft 14 for connection with power supply 18 in order to transmit or supply electric current from the power supply 18 to the transducer 20. The power supply 18 may be disposed partly or entirely in the handle 17, or may be provided separately as a console or unit coupled to the handle shaft 14 or to handle 17 via one or more appropriate transmission wires, which may be the same or different from the one or more transmission wires 42. For example, an electrical cord of suitable length may be removably coupled between the handle 17 and the power supply 18. The power supply 18 can be designed in various ways as a source or supply of electricity to activate or excite transducer 20 to generate and emit ultrasound energy. For example, the power supply 18 is designed to provide high frequency alternating electrical current to the transducer 20 via the one or more transmission wires 42. The power supply 18 may include an RF generator, with or without an amplifier, providing a constant current source. Electrical current provided by the power supply 18 is selectively discharged into all or selected ones of the piezoelectric elements 24, producing vibration of all or selected ones of the element 24 and, therefore, producing acoustic or ultrasonic waves or energy. The power supply 18 may be separate from the handle 17 but may be operated via controls 33 of handle 17.

In the case of focused ultrasound ablation device 11, a transmission wire 42 is provided for each piezoelectric element 24. As shown in Fig. 2, each transmission wire 42 is connected to its corresponding piezoelectric element 24 and to the power supply 18 so that the transducer elements 23 are individually driven by or supplied with current from the power supply 18. The transmission wires 42 are disposed in respective passages within housing 22 and may be disposed within a sheath or sleeve 36 extending through shaft 14. The transmission wires 42 are connected to switches (not shown), respectively, for controlling the supply or transmission of current from the power supply 18 to the piezoelectric elements 24, respectively. The switches can be incorporated in the ultrasound emitting member 12, the power supply 18 or the controller 44.

The controller or control unit 44, shown schematically in Fig. 1, controls the supply of power from power supply 18 to transducer 20 so that the transducer 20 can be driven to deliver various intensity levels of ultrasound energy for various durations, periods or lengths of time. In particular, the controller 44 controls the supply of power from power supply 18 to the individual piezoelectric elements 24 so that the transducer elements 23 can be individually driven or actuated to emit ultrasound energy. The controller, which may be designed as part of the power supply 18, will typically include a control panel and display monitor, a switch for current control, an input mechanism such as a keyboard, and/or a microprocessor including memory, storage and data processing capabilities for performing various functions. The controller 44 is capable of selectively activating the switches to effect actuation of all or selected ones of the plurality of transducer elements 23. For example, switches on the controller 44 and/or the controller keyboard can be used to selectively couple and decouple the individual transducer elements 23 with the electrical

drive signal or current from the power supply 18. In put to the controller 44 provided by the surgeon or other medical personnel determines the transducer elements 23 to be actuated. For example, data entered via the controller keyboard is used to identify the particular transducer elements 23 to be actuated, the transducer elements 23 being identified, for example, by their location or position in the array as explained above. In this manner, the switches of selected transducer elements 23 can be activated to permit transmission of electrical current from the power supply 18 to the piezoelectric elements 24 of the selected transducer elements while the switches of other selected transducer elements 23 can remain deactivated to prevent transmission of electrical current thereto when the power supply is actuated or switched to an "on" mode. It should be appreciated that various components and/or methodology can be incorporated in the device 11, including the power supply 18 and/or the controller 44, to permit selective actuation of selected ones of the transducer elements 23 and that such components and/or methodology would be within the purview of one skilled in the art.

Various transducers can be used in the focused ultrasound ablation devices of the present invention. The transducer can include an annular array, a linear array and/or a curved linear array of transducer elements. The piezoelectric elements can be made of various piezoelectric materials such as PZT crystal materials, hard lead, zirconate/lead titanium piezoelectric ceramic, or lithium-niobate piezoceramic material. The array of piezoelectric elements can be of various sizes or surface configurations to obtain lesions of various sizes with an array of larger surface area generally providing more ultrasound energy and a larger lesion size than an array of smaller surface area. The frequency ranges of the transducer and/or the individual transducer elements can vary depending on

clinical needs. Preferably, the transducer frequency will allow thermal ablation of anatomical tissue to be effected at the target area in response to the application or delivery of ultrasound energy for a relatively short duration or length of time.

It should be appreciated that the high intensity focused ultrasound ablation device 11 can be provided with imaging capabilities for visualizing an operative site at which the focused ultrasound ablation device 11 is to be used, for visualizing guidance and/or positioning of the ultrasound emitting member 12 at the operative site and/or for examination and diagnosis. The focused ultrasound ablation device 11 can be designed to provide the imaging capabilities and can thusly be used for both therapy and imaging. Observation of a detected image can be obtained at a location remote from the operative site. For example, the ultrasound emitting member 12 can be provided with an ultrasound imaging transducer as described in the applications incorporated herein by reference. Conventional optical guidance mechanisms, such as fiber optic mechanisms, can be used in or with the high intensity focused ultrasound ablation device 11, such as in or on the focused ultrasound ablation device 11, to provide remote visualization, and such optical guidance mechanisms can be separate from or formed as part of the ultrasound emitting members. The high intensity focused ultrasound ablation device can be provided with a viewing device such as an eyepiece on the handle shaft or on the handle or a video monitor for viewing an image of the operative site from the remote location, typically externally of the patient's body.

The focused ultrasound ablation devices of the present invention is used to ablate a target or lesion area within a larger mass, body or area of tissue to create an internal ablative lesion that is capable of being naturally degraded and absorbed by a patient's

body. As the lesion is absorbed, the tissue shrinks or decreases in size. In this manner, the size or volume of the mass, body or area of tissue can be reduced and/or the configuration of the mass, body or area of tissue can be changed for various therapeutic purposes.

In a thermal ablation procedure utilizing focused ultrasound ablation device 11, the controller 44 is instructed to effect actuation of selected transducer elements 23 in accordance with the size and/or pattern of a lesion desired to be formed in tissue of a particular patient. In the procedure illustrated in Fig. 2, all of the transducer elements 23 are to be actuated; and, accordingly, input to the controller 44 made by the surgeon or other medical personnel designates all of the transducer elements 23 to be actuated by the power supply 18 to obtain a lesion of continuous surface area. The surface or active face 34 is positioned in contact with an external tissue surface 41 of tissue A of the patient at a location or operative site on tissue A corresponding to or aligned with a desired location or site for a subsurface lesion as shown in Fig. 2. Once the surface 34 is positioned in contact with the tissue A at the desired location, the power supply 18 is activated or switched to an "on" mode, such as by depressing a pushbutton 33. Since all of the transducer elements 23 have been designated or selected for actuation, electrical energy is transmitted from the power supply 18 to each piezoelectric element 24 via the transmission wires 42. In response thereto, the piezoelectric elements 24 vibrate and produce ultrasound energy which, due to the curved configuration of the piezoelectric elements 24, is focused at focusing zones P, within the tissue A. Accordingly, anatomical tissue A at the focusing zones P is heated to an ablative temperature and spreads or disseminates throughout the lesion or target area 28 causing a bioabsorbable subsurface or internal

ablative lesion 30 to be formed in the tissue A at the target area 28 while the ultrasound emitting member 12 remains external of and does not physically penetrate the tissue A. In addition, tissue surrounding the target area 28 is not heated to damaging levels and is thusly preserved. The lesion 30 has a length, width and depth of known parameters dictated by the configuration of the array, the intensity of the ultrasound energy and the duration of ultrasound energy delivery or application to the tissue. The lesion can have various continuous or discontinuous configurations, including rectangular, square and circular configurations depending on the surface configuration of the array and/or the pattern presented by the transducer elements selected for actuation. Since the transducer elements 23 are arranged in a rectangular array, the lesion 30 is continuous or solid along a rectangular surface configuration, as shown in Fig. 3, when all the transducer elements 23 are actuated.

Due to the predetermined distance D for the focusing zones and the known parameters for the lesion 30 capable of being obtained with the transducer 20, the lesion 30 begins at a beginning or starting margin 46 located a predetermined or known depth beneath or below the external tissue surface 41 and ends at an ending margin 47 located a predetermined or known depth beneath the external tissue surface 41. The distance between the beginning and ending margins corresponds to the depth of the lesion. By selecting a transducer with the appropriate focusing zone depth in the tissue, a desired preselected thickness or depth of tissue between the beginning margin 46 and the external tissue surface 41 is disposed outside the target area 28 and is therefore undamaged and preserved. Although the length and width or other external dimensions of the lesion can be determined by the configuration of the array and/or by actuation of selected transducer

elements 23, it should be appreciated that the external dimensions of the lesion can alternatively be obtained by moving the member 12 from point to point on the tissue as described in the co-pending patent applications incorporated herein by reference.

The emission of ultrasound energy by ultrasound emitting member 12 is terminated by the surgeon or other operator once a desired lesion size or amount of tissue ablation has been obtained, and the member 12 is removed from the tissue A. In order to terminate the emission of ultrasound energy by ultrasound emitting member 12, the power supply 18 is deactivated or switched to an "off" mode, such as via a pushbutton 33, so that electrical current is no longer supplied to the piezoelectric elements 24. Where one or more additional lesions are to be formed in tissue A or other tissue of the patient, the member 12 is repositioned on the tissue A or is positioned on the other tissue at another selected location or operative site, and the procedure is repeated. The lesion 30 will be naturally degraded and absorbed by the patient's body in due course, and the remaining tissue A will be smaller in bulk, size or volume than it was prior to treatment.

Fig. 4 illustrates focused ultrasound emitting member 12 when the transducer elements 23 in the outermost rows and columns of the array are not activated to emit ultrasound energy, the activated transducer elements 23 being shaded in Fig. 4. In particular, the transducer elements 23 of columns one and six and rows one and five are not actuated while the remaining transducer elements 23 are actuated to emit ultrasound energy by the power supply 18 as selected and controlled via the controller 44 as described above. The activated transducer elements 23 form a rectangular pattern or sub-array forming a subsurface lesion 130 in tissue A as shown in Fig. 5. The lesion 130 is

similar to the lesion 30 except that the lesion 130 is continuous or solid along a rectangular surface configuration smaller than the rectangular surface configuration for lesion 30.

Fig. 6 is illustrative of a discontinuous "firing" pattern for the array of transducer elements 23. Fig. 6 shows the focused ultrasound emitting member 12 with selected transducer elements 23 activated to emit ultrasound energy, the activated transducer elements 23 being shaded. In Fig. 6, the transducer elements 23 at locations R2C1, R3C1, R4C1, R2C3, R3C3, R4C3, R2C4, R3C4, R4C4, R2C6, R3C6 and R4C6 are actuated to emit ultrasound energy while the remaining transducer elements 23 are decoupled from the power supply 18. Fig. 7 illustrates a lesion 230 obtained with ultrasound emitting member 12 when the transducer elements 23 are "fired" in the pattern shown in Fig. 6. As shown in Fig. 7, a discontinuous lesion 230 is formed in tissue A, the lesion 230 comprising separate, disconnected lesion segments 230a, 230b and 230c. Lesion segment 230b is centrally located between lesion segments 230a and 230c and has a length and width corresponding or substantially corresponding to the length and width of a rectangular sub-array formed by the transducer elements 23 at locations R2C3, R2C4, R3C3, R3C4, R4C3 and R4C4. Accordingly, lesion segment 230b is continuous or solid along a surface area of rectangular configuration. Lesion segments 230a and 230c are similar to one another and are disposed on opposite sides of lesion segment 230b. Lesion segments 230a and 230c are spaced from lesion segment 230b, and the tissue segments between lesion segment 230b and lesion segments 230a and 230c, respectively, are undamaged and preserved. Lesion segment 230a has a length and width corresponding or substantially corresponding to the length and width of a sub-array formed by the transducer elements 23 at locations R2C1, R3C1 and R4C1. Lesion segment 230c

has a length and width corresponding or substantially corresponding to the length and width of a sub-array formed by transducer elements 23 at locations R2C6, R3C6 and R4C6. The lesion segments 230a and 230c are each solid or continuous along a surface area of rectangular configuration, the lesion segments 230a and 230c having the same length as lesion segment 230b but having a width smaller or less than the width of lesion segment 230b.

An alternative focused ultrasound ablation device according to the present invention is illustrated at 211 in Fig. 8. Focused ultrasound ablation device 211 is similar to focused ultrasound ablation device 11 except that the transducer elements 223 of the focused ultrasound emitting member 212 of device 211 are arranged in rows R that are staggered or offset from one another. In particular, the array formed by transducer elements 223 has a generally rectangular configuration with five rows of transducer elements 223, the transducer elements 223 of rows two and four being vertically offset from or not aligned with the transducer elements of rows one, three and five. In addition, the rows R do not contain an equal number of transducer elements 223, rows one, three and five containing six transducer elements 223 and rows two and four containing five transducer elements 223. As described for focused ultrasound emitting member 12, all or selected ones of the transducer elements 223 can be actuated to emit ultrasound energy.

With the present invention, a single focused ultrasound ablation device can be used to form lesions of various sizes and/or configurations or patterns in anatomical tissue via actuation of selected transducer elements of the focused ultrasound emitting member. In this manner, lesion size and/or configuration can be optimally selected for individual patients. The lesions formed in accordance with the present invention can be continuous

or solid, or the lesions can be comprised of disconnected lesion segments. Where lesions comprised of disconnected lesion segments are formed in anatomical tissue, thermal damage to the tissue disposed between, around or surrounding the individual lesion segments can be avoided. Since various sizes and/or configurations or patterns of lesions can be obtained with a singled focused ultrasound ablation device, a single focused ultrasound ablation device can be used to ablate various types of anatomical tissue or structures at various operative sites within or on patients' bodies. The high intensity focused ultrasound ablation device of the present invention can thusly be provided as a standardized device capable of being used in diverse thermal ablation procedures.

Inasmuch as the present invention is subject to many variations, modifications and changes in detail, it is intended that all subject matter discussed above or shown in the accompanying drawings be interpreted as illustrative only and not be taken in a limiting sense.